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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/433,418	11/04/1999	JOEL B. EPSTEIN	244/023	2559

7590 05/21/2003

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EXAMINER	
BAHAR, MOJDEH	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/21/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/433,418	EPSTEIN, JOEL B.	
	Examiner	Art Unit	
	Mojdeh Bahar	1617	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,12-19,21-28 and 30-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-10,12-19,21-28 and 30-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's response to the office action of June 5, 2002 is acknowledged. Applicant's amendment and remarks have overcome the rejections under 35 USC 102 and 112 in the previous office action.

Claim Objections

Claims 37-39 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Note that independent claim 1 recites the close transitional phrase "consisting of", EXCLUDING ALL ACTIVE PHARMACEUTICAL AGENTS OTHER THAN THE ONE REQUIRED ACTIVE AND ONE OPTIONAL ACTIVE. Yet claims 37-39 which depend from claim 1 recite a composition "further comprising".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-10, 12-19, 21-28, 30-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hewitt et al. (USPN 5,540,931), Lozada, and Sharpe et al. (USPN 5,637,616)

Hewitt et al. (USPN 5,540,931) teaches topical compositions for site-specific immune suppression comprising one or more immunosuppressants, e.g., azathioprinse, cyclophosphamide, didemnin B, deoxyspergualin. Methotrexate, thalidomide, or combinations

thereof, see claims 1-7. Hewitt et al. also teaches the employment of hydrocortisone in its formulation, see claims7-9. Hewitt finally teaches that some conditions may require topical immunosuppresion alone, see col. 9, lines 19-21 for example.

Lozada teaches a method of treating patients with chronic inflammatory mucocutaneous disease having oral ulcerations including lichen planus, pemphigus vulgaris and bullous pemphigoid comprising administering azathioprine (an immunosuppressive agent), and a steroidal antiinflammatory agent see page 257 first full paragraph, see also MATERIALS AND METHODS. Lozada teaches that Azathioprine is administered from 5 mg every other day to 100 mg/day, see pages 258 Drugs and Results. See also page 259, Col. 2, first full paragraph as well as page 258 Adverse effects.

Sharpe et al. (USPN 5,637,616) teaches a method for topical treatment of mucosal lesions and in particular bullous pemphigoid, lichen planus, and aphthous ulcers employing gel, ointment, cream, foam, lotion or a solution that is orally applied, swished and expectorated or swallowed, see in particular claims 5-13. Sharpe et al. (USPN 5,637,616) also teaches that topical corticosteroids are known to be employed in treating aphthous ulcers, see col. 4, lines 41-47. Sharpe et al. (USPN 5,637,616) also teaches that bullous pemphigoid is known to be treated with immunosuppressive agents in addition to steroids and pemphigus is known to be treated with corticosteroids, such as prednisone and prednisolone as well as immunosupressive agents such as azathioprine, cyclosphamide, methotrexate and cyclosporine, see col. 3, lines 23-30; see also col. 2, 62-col. 3, line 4. Sharpe et al. also teaches the employment of anti-inflammatory agents in its composition, see in particular col. 10 lines 51-56. Finally, Sharpe et al. teaches that these oral lesions are accompanied by pain, see col 1, lines 39-43, see also col. 5, lines 32-36.

Hewitt, Lozada and Sharpe et al. (USPN 5,637,616) taken together, do not particularly teach the incorporation of NSAIDS in their methods.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ azathioprine (an immunosuppressive agent), and corticosteroids in a topical formulation employed in a method of treating autoimmune diseases of the mouth. It would have also been obvious to employ NSAIDS in their method.

One of ordinary skill in the art would have been motivated to employ azathioprine (an immunosuppressive agent), and corticosteroids in a topical formulation employed in a method of treating autoimmune diseases of the mouth because both agents individually are known to be useful in treating autoimmune diseases of the mouth. Combining two agents which are known to be useful to in treating autoimmune disease of the mouth individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. Further the oral lesions symptomatic of autoimmune diseases of the mouth are known to be painful. The skilled artisan would have been motivated to add NSAIDS to formulations known to be useful in treating autoimmune diseases of the mouth because pain is known to be associated with these oral lesions. Optimization of amounts is within the purview of the skilled artisan and is therefore obvious.

Response to Arguments

Applicant's arguments filed December 9, 2002 have been fully considered but they are not persuasive. Since the Eggleston reference is withdrawn to applicant's amendment and remarks, the portion of the arguments based on Eggleston, i.e., page 6 of the response, is moot. Applicant argues that the claims herein contain the closed transitional phrase "consisting of" and

all the cited prior art references have more actives than those claimed herein. Note that although the closed transitional phrase "consisting of" obviates an anticipation rejection, it does not overcome an obviousness rejection. The cited references together teach that topical formulations of corticosteroids, immunosuppressive agents, and anti-inflammatory agents are known to be useful in treating different immune diseases of the mouth. Therefore employing any combination of these agents employed in a method of treating immune diseases of the mouth would also be obvious.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan., can be reached on (703) 305-1877. The fax number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
May 17, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER
5/19/03